

The following comments by William T. Godshall, MPH, and Smokefree Pennsylvania are submitted to the Food and Drug Administration (FDA) Tobacco Product Scientific Advisory Committee (TPSAC) for its January 18-20, 2012 meeting and its forthcoming study and report on dissolvable tobacco products. Submitted January 3, 2012.

Legal and Regulatory Scope of Dissolvable Tobacco Products

Pursuant to Judge Richard Leon's ruling in the Sottera, Inc v FDA at https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2009cv0771-54 and the FDA's April, 25, 2011 statement agreeing to comply with Judge Leon's ruling at <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm252360.htm> any product containing nicotine that is intended for human consumption can be marketed as a tobacco product as long as the manufacturer or importer makes no therapeutic claim.

Therefore, the TPSAC should consider ALL dissolvable tobacco and nicotine products, including Nicotine Replacement Therapy (NRT) products, in its forthcoming study and report on dissolvable tobacco products.

Since the FDA notified Star Scientific, Inc. in March, 2011 that Chapter IX of the Family Smoking Prevention and Tobacco Control Act (FSPTCA) http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_public_laws&docid=f:publ031.111.pdf doesn't apply to two of the company's dissolvable tobacco products [Ariva-BDL and Stonewall-BDL] (presumably because they don't meet the definition of a smokeless tobacco product) <http://www2.journalnow.com/news/2011/mar/24/wsbiz01-two-tobacco-products-free-of-fda-oversight-ar-886868/>, since dissolvable nicotine products also probably don't meet the definition of a smokeless tobacco product, and because other dissolvable tobacco products may not meet the definition of a smokeless tobacco product, it would be wise for the TPSAC to realize that Chapter IX of the FSPTCA may not apply to some/many/most/all dissolvable tobacco products.

Dissolvable Tobacco Products are Similar to Dissolvable NRT Products

At the FDA's 2010 workshop entitled: Risks and Benefits of Long-Term Use of Nicotine Replacement Therapy (NRT) Products; Public Workshop <http://www.regulations.gov/#!documentDetail;D=FDA-2010-N-0449-0001;oldLink=false> many presenters and commenters (including two TPSAC members) cited the similarities between Swedish snus and NRT products in suggesting that Swedish snus studies be considered for evaluating the long term risks and benefits of NRT usage (since longterm studies on NRT aren't available because the products have only been on the market for several decades).

Since dissolvable tobacco products have been on the market for the past decade, and since these products also closely resemble Swedish snus, the TPSAC should also consider research on Swedish snus in evaluating dissolvable tobacco products.

A study evaluating plasma nicotine levels, heart rates, and reduction in cigarette cravings following use of Star's Ariva dissolvable tobacco product were very similar to those following use of GlaxoSmithKline's Commit dissolvable nicotine product. Meanwhile, participants reported that Star's Ariva tasted better than GSK's Commit.

Evaluating the Acute Effects of Oral, Non-combustible Potential Reduced Exposure Products Marketed to Smokers, Caroline O Cobb, Michael F Weaver, Thomas Eissenberg, Tob Control
doi:10.1136/tc.2008.028993

http://static.mgnetwork.com/rtd/pdfs/20090712_toba.pdf (**Appendix A**)

Another study found that Star's Ariva and Stonewall dissolvable tobacco products contained far lower levels of tobacco specific nitrosamines than various American moist snuff products and several Swedish snus products, and that nitrosamine levels in Star's Ariva and Stonewall were just slightly higher than nitrosamine levels in GlaxoSmithKline's Nicorette gum and Nicoderm CQ skin patch.

Tobacco-specific nitrosamines in new tobacco products, Irina Stepanov, Joni Jensen, Dorothy Hatsukami, Stephen S. Hecht, Nicotine and Tobacco Research Volume 8, Number 2 (April 2006) 309-313.

<http://www.starscientific.com/404/stepanov%20tsna%20in.pdf> (**Appendix B**)

Another more recent study by Stepanov et al similarly found that new dissolvable tobacco products marketed by RJ Reynolds (i.e. Camel Orbs, Strips and Sticks) contain very low levels of tobacco specific nitrosamines, while nicotine levels vary.

Monitoring Tobacco-Specific N-Nitrosamines and Nicotine in Novel Marlboro and Camel Smokeless Tobacco Products: Findings From Round 1 of the New Product Watch; Irena Stepanov et al, Nicotine & Tobacco Research, doi10.1093/ntr/ntr209

(**Appendix C**)

Dissolvable tobacco products appear to be even more similar to dissolvable NRT lozenges than they are to Swedish Snus. In their 2001 Citizen Petition urging the FDA declare and regulate Star's Ariva as a drug (instead of as a tobacco product), the National Center for Tobacco Free Kids (CTFK), American Cancer Society (ACS), American Heart Association (AHA), American Legacy Foundation (ALF) and others argued that Star's Ariva was strikingly similar to NRT products that are approved by the FDA to be marketed as smoking cessation aids.

ALL Smokefree Tobacco Products Marketed in the U.S. and Sweden are Far Less Hazardous Alternatives to Cigarettes

While cigarettes and smokefree tobacco products are similarly addictive (i.e. creating daily dependence), published epidemiology research finds that daily cigarette smoking imposes about 100 times greater mortality risks than does daily use of smokefree tobacco products marketed in the U.S. and Sweden. On a continuum of tobacco mortality risk from 1 to 100 (whereby NRT products are 1 and cigarettes are 100), smokefree tobacco products are below 2.

Nearly five years, two comprehensive evaluations of epidemiology research confirmed that smokeless tobacco products are exponentially less hazardous than cigarette smoking, and recommended that smokers be provided with truthful information about the

comparable health risks of different tobacco products and encouraged to switch to smokefree tobacco alternatives if they cannot or don't want to quit using tobacco. *Tobacco harm reduction: an alternative cessation strategy for inveterate smokers*, Brad Rodu and William T Godshall, *Harm Reduction Journal* 2006, 3:37doi:10.1186/1477-7517-3-37. <http://www.harmreductionjournal.com/content/3/1/37> (**Appendix D**)

Harm reduction in nicotine addiction; Helping people who can't quit, Royal College of Physicians, 2007.
<http://www.rcplondon.ac.uk/pubs/contents/e226ee0c-ccef-4dba-b62f-86f046371dfb.pdf>

Brad Rodu recently wrote an updated review of the scientific evidence for tobacco harm reduction published from 2006 to 2011, which corroborates and provides significantly more evidence that smokeless tobacco products in America and Sweden are far less hazardous than cigarettes, and that many smokers have quit smoking or have significantly reduced cigarette consumption by substituting smokefree tobacco alternatives. *The scientific foundation for tobacco harm reduction, 2006-2011*; Brad Rodu, *Harm Reduction Journal* 2011, 8:19.
<http://www.harmreductionjournal.com/content/pdf/1477-7517-8-19.pdf> (**Appendix E**)

Authors of a recent comprehensive meta analysis of North American and European epidemiological cohort and case-control studies relating any form of cancer to smokeless tobacco use (i.e. 62 US and 18 Scandinavian studies) reported the following results:

“Random-effects meta-analysis estimates for most sites showed little association. Smoking-adjusted estimates were only significant for oropharyngeal cancer (1.36, CI 1.04–1.77, $n = 19$) and prostate cancer (1.29, 1.07–1.55, $n = 4$). The oropharyngeal association disappeared for estimates published since 1990 (1.00, 0.83–1.20, $n = 14$), for Scandinavia (0.97, 0.68–1.37, $n = 7$), and for alcohol-adjusted estimates (1.07, 0.84–1.37, $n = 10$). Any effect of current US products or Scandinavian snuff seems very limited. The prostate cancer data are inadequate for a clear conclusion.”

“Some meta-analyses suggest a possible effect for oesophagus, pancreas, larynx and kidney cancer, but other cancers show no effect of smokeless tobacco. Any possible effects are not evident in Scandinavia. Of 142,205 smoking-related male US cancer deaths in 2005, 104,737 are smoking-attributable. Smokeless tobacco-attributable deaths would be 1,102 (1.1%) if as many used smokeless tobacco as had smoked, and 2,081 (2.0%) if everyone used smokeless tobacco.”

Systematic review of the relation between smokeless tobacco and cancer in Europe and North America, Peter N Lee and Jan Hamling, *BMC Medicine* 2009, 7:36doi:10.1186/1741-7015-7-36
<http://www.biomedcentral.com/1741-7015/7/36>

A previous meta analysis of smokeless tobacco similarly found that the use of smokeless tobacco products pose far fewer cancer risks than does cigarette smoking.

Smokeless tobacco and cancer, Boffetta P, Hecht S, Gray N, Gupta P, Straif K, *Lancet Oncol*, 2008 Jul;9(7):667-75.
http://www.ncbi.nlm.nih.gov/pubmed/18598931?ordinalpos=27&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DefaultReportPanel.Pubmed_RVDocSum

Another recently published comprehensive meta analyses of 150 studies on various diseases found no association with snus use and cancer of the oropharynx (meta-analysis RR 0.97, 95% CI 0.68-1.37), oesophagus (1.10, 0.92-1.33), stomach (0.98, 0.82-1.17), pancreas (1.20, 0.66-2.20), lung (0.71, 0.66-0.76) or other sites, or with heart disease (1.01, 0.91-1.12) or stroke (1.05, 0.95-1.15). The author concluded: “Using snus is clearly much safer than smoking. While smoking substantially increases the risk of cancer and cardiovascular diseases, any increase from snus use is undemonstrated, and if it exists is probably about 1% of that from smoking.”

Summary of the epidemiological evidence relating snus to health, Peter N Lee, Regul Toxicol Pharmacol 2011, Mar, 59(2):197-214 <http://www.ncbi.nlm.nih.gov/pubmed/21163315>

A previously published meta analysis of 11 studies found that snus use was associated with slightly elevated risk of fatal myocardial infarction and fatal stroke, but wasn't associated with all myocardial infarctions or strokes, casting doubt on its findings about fatal heart attacks and strokes.

Use of smokeless tobacco and risk of myocardial infarction and stroke: systematic review with meta-analysis, Paulo Boffetta, Kurt Straif, BMJ 2009; 339:b3060

<http://www.bmj.com/content/339/bmj.b3060.full>

Millions of Smokers Have Already Switched to Smokefree Tobacco Products

Switching from cigarettes to smokefree tobacco products has been occurring in the U.S. and in Sweden for many decades, and isn't an unproven theory (as some harm reduction denialists claim).

The 1986 nationwide Adult Use of Tobacco Survey (AUTS), conducted by the CDC Office on Smoking and Health, found that 7% (i.e., 1.67 million) of male ex-smokers indicated they had used smokeless tobacco (ST) products to help them quit smoking cigarettes, and 6.4% (i.e., 1.63 million) of males who currently smoked indicated using ST to help them quit smoking. In comparison, just 1.7% of male ex-smokers (i.e., 404,600) and 2.4% of males who currently smoked (i.e., 609,000) indicated using organized programs to help them quit smoking cigarettes.

Smokeless Tobacco Use in the United States: The Adult Use of Tobacco Surveys, Novotny, Pierce, Fiore & Davis, NCI Monograph 8, 25-29, NIH, U.S. DHHS, 1989.

A 1984 Philip Morris market research survey of 489 adult male ST product users in Houston, Atlanta, and Florida (who were interviewed outside retail stores after purchasing ST) found that 37% of ST users stated they were former cigarette smokers (including 22% of those under age 35 and 50% of those 35 years or older). The survey also found that, in response to the question, “Did you start using smokeless/chewing tobacco as a replacement for cigarettes, that is, when you stopped smoking cigarettes, or not?” 20% of ST users said YES (including 11% of those under age 35 and 27% of those 35 years or older). These findings were consistent in the three different survey locations. Interestingly, 62% of respondents who used both ST and cigarettes reported that ST was “*more enjoyable*” than cigarettes.

Smokeless Tobacco Study – Atlanta/Florida, Philip Morris USA Marketing Research Department Report, Miller K, <http://tobaccodocuments.org/pm/2045600026-0045.html>

The 1991 NHIS found that 33.3% (i.e., 1.75 million) of U.S. adult ST users reported being former cigarette smokers, and the 1998 NHIS found that 31.1% of ST users reported being former cigarette smokers. The 1998 NHIS found that 5.8% of daily snuff users reported quitting smoking cigarettes within the past year, that daily snuff users were 3.2 times more likely to report being former cigarette smokers than were never snuff users who had smoked, and that daily snuff users were 4.2 times more likely to have quit smoking in the past year than were never snuff users who had smoked.

Use of Smokeless Tobacco Among Adults – United States, 1991, Morbidity and Mortality Weekly Report, Vol 42, No 14, 263-266, April 16, 1993, CDC, U.S. DHHS.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/00020232.htm>

Tomar S, Snuff Use and Smoking in US Men: Implications for Harm Reduction, American Journal of Preventive Medicine, 2002, Vol. 23, No. 3, 143-149.

A study of 1226 male high school baseball players in California found that 33% of the 184 current ST product users were former cigarette smokers.

Walsh MM, Ellison J, Hilton J, et al, Spit (smokeless) tobacco use by high school baseball athletes in California, Tobacco Control 2000;9(Suppl II):ii32-ii39 (Summer).

http://tc.bmjjournals.com/cgi/search?andorexactfulltext=and&resourcetype=1&disp_type=&sortspec=relevance&author1=Walsh&fulltext=smokeless+tobacco&volume=9&firstpage=

The 1987 NHIS found that, among 23-to-34 year old U.S. males, those who had smoked cigarettes and then subsequently used snuff were 2.1 times more likely to have quit smoking than were cigarette-only users.

Most smokeless tobacco use is not a causal gateway to cigarettes: using order of product use to evaluate causation in a national US sample, Kozłowski L, O'Connor, Edwards BQ, Flaherty BP, Addiction, 2003, Vol. 98, 1077-1085. <http://www.blackwell-synergy.com/links/doi/10.1046/j.1360-0443.2003.00460.x/abs>

A study of 51 female and 59 male SLT users (in the Northwestern U.S.), in which 98% of females and 90% of males were either current or former cigarette smokers, found that 52% of females and 59% of males responded affirmatively when asked whether they used ST in place of cigarettes while quitting smoking.

A comparison of male and female smokeless tobacco use, Cohen-Smith D, Severson H, Nicotine & Tobacco Research, 1999, Vol. 1, 211-218.

Another study found that 72% of an estimated 359,000 U.S. smokers who switched to ST products on their last smoking cessation attempt successfully quit smoking.

Switching to smokefree tobacco as a smoking cessation method: evidence from the 2000 National Health Interview Survey, Brad Rodu and Carl V Phillips, Harm Reduction Journal 2008, 5:18doi:10.1186/1477-7517-5-18. <http://www.harmreductionjournal.com/content/pdf/1477-7517-5-18.pdf>

In Sweden, moist oral snuff is called snus. Unlike moist oral snuff commonly used in the U.S., snus is pasteurized, not fermented, and stored in refrigerators from the time of manufacture until sold at retail. Also in contrast to most ST products commonly sold in the U.S. (except for dissolvable ST products), snus is spitfree, contains fewer nitrosamines, and has not been found to be associated with mouth cancer.

Effect of smokeless tobacco (snus) on public health in Sweden, Foulds J, Ramstrom L, Burke M, Fagerstrom K, Tobacco Control, 2003, Vol 12, 349-359. <http://tc.bmjjournals.com/cgi/content/full/12/4/349>

Smokeless tobacco use and increased cardiovascular mortality among Swedish construction workers. Bolinder G, Alfredsson L, Englund A, et al., Am J Public Health 1994, Volume 84, 399-404.
Smoking tobacco, oral snuff and alcohol in the etiology of squamous cell carcinoma of the head and neck. A population based case-referent study in Sweden. Lewin F, Norell SE, Johansson H, et al, 1998, Cancer, Vol. 82, 1367-1375.
Oral snuff, smoking habits and alcohol consumption in relation to oral cancer evaluated in a Swedish case-control study, Schildt E-B, Eriksson M, Hardell L, Magnusson A, 1998, International Journal of Cancer, Vol. 77, 341-346.

When a large national sample of Swedish ex-smokers was asked about how they succeeded in quitting, 50% stated that they had stopped without help, 33% said they used snuff, and 17% said they had used some form of NRT.

Smokeless Tobacco and Cardiovascular Disease, Asplund, K, Progress in Cardiovascular Diseases, Vol. 45, No 5, (March/April) 2003, 383-394.

Another survey of more than 6,700 Swedes found that more than 25% of male cigarette smokers indicated they had switched to snus. The survey also found that snus was more effective than NRT products as a smoking cessation aid.

Role of snus in initiation and cessation of tobacco smoking in Sweden, Ramström and Foulds Tob Control.2006; 15: 210-214. <http://tobaccocontrol.bmj.com/cgi/content/full/15/3/210>

Largely due to smokers switching to snus, the male cigarette smoking rate in Sweden dropped from 40% in 1976 to just 15% in 2002, while snus use among Swedish men increased from 10% to 23%. Due to this decline in smoking, male lung cancer rates in Sweden are the lowest in Europe, while Sweden's oral cancer rate has fallen during the last 20 years as snus use sharply increased.

Effect of smokeless tobacco (snus) on public health in Sweden, Foulds J, Ramstrom L, Burke M, Fagerstrom K, Tobacco Control, 2003, Vol 12, 349-359. <http://tc.bmjournals.com/cgi/content/full/12/4/349>

An international panel of seven experts, using the Delphi approach, estimated that an additional 10% of cigarette smokers would quit over five years if all smokefree tobacco products in the U.S. were required to be low-nitrosamine products and if those products were accompanied by a warning label that stated: "This product is addictive and may increase your risk of disease. This product is substantially less harmful than cigarettes, but abstaining from tobacco use altogether is the safest course of action."

The potential impact of a low-nitrosamine smokeless tobacco product on cigarette smoking in the United States: Estimates of a panel of experts, Levy D, Mumford E, Cummings KM, et al. Addictive Behaviors, Nov. 2005. <http://www.ascribe.org/cgi-in/behold.pl?ascribeid=20051114.171444&time=07%2042%20PST&year=2005&public=1>

Authors of a recent survey of Norwegian men who were either former or current smokers reported: "In a regression model in which education, number of previous attempts to quit smoking, perception of risk, and age were controlled for, the odds ratio (OR) for reporting total abstinence at the time of the survey was significantly higher for those who had used varenicline (OR = 4.95, $p < .006$) and snus (OR = 2.68, $p < .001$) compared with those who had used nicotine chewing gum (reference OR = 1)." and "Compared with medicinal nicotine products, snus and varenicline increased the probability of quitting smoking completely".

The use of snus for quitting smoking compared with medicinal products, Karl Erik Lund, Ann McNeill, Janne Scheffels, Nicotine Tob Res (2010) doi: 10.1093/ntr/ntq105

<http://ntr.oxfordjournals.org/content/early/2010/07/09/ntr.ntq105.full.pdf+html>

Safety of Dissolvable Tobacco Products

A recently published article, which has been widely publicized by abstinence-only advocates who oppose tobacco harm reduction, alleged that dissolvable tobacco products (which the author's repeatedly referred to as candy-like) are potentially toxic to children and that thousands of cases of ingestion of tobacco products has been reported.

Unintentional Child Poisonings Through Ingestion of Conventional and Novel Tobacco Products, Gregory N Connolly, Patricia Richter, Alfred Aleguas Jr, Terry Pechacek, Stephen Stanfill, Hilbert Albert, *Pediatrics* 2009-2835.

<http://pediatrics.aappublications.org/content/early/2010/04/19/peds.2009-2835.abstract>

In rebutting the alarmist claims made in the Connolly et al article, Brad Rodu revealed that, according to the 2008 report of the American Association of Poison Control Centers, all types of tobacco products only accounted for 1% of all reported exposures to non-pharmaceutical agents of all kinds in children less than 6 years of age, and that smokeless tobacco products accounted for just 15% of the reported tobacco exposures.

Poisoning Public Health Issues, Brad Rodu, *Tobacco Truth*, April 19, 2010

<http://rodutobaccotruth.blogspot.com/2010/04/poisoning-public-health-issues.html>

Earlier this year, a comprehensive analysis of the past 27 annual reports by the American Association of Poison Control Centers thoroughly rebutted the fearmongering claims made by Connolly et al, and found that many other consumer products pose far greater risks of accidental ingestion and poisoning than do tobacco products.

Frequency and outcomes of accidental ingestion of tobacco products in young children.

Scott Appleton, *Regul. Toxicol. Pharmacol.* (2011), doi: 10.1016/j.yrtph.2011.07.010

(Appendix F)

Since all tobacco products (including dissolvables and NRT) pose potential risks, all tobacco products (and NRT products) should be kept away from children.

Most Smokers Incorrectly Believe Smokeless Tobacco Products are as Hazardous as Cigarettes

While ST products are far less hazardous alternatives to cigarettes, a recent survey of more than 13,000 cigarette smokers in the US, Canada, UK and Australia found that only 13% correctly believed that ST products are less hazardous than cigarettes.

Smokers' beliefs about the relative safety of other tobacco products: Findings from the ITC Collaboration, Richard J. O'Connor; Ann McNeill; Ron Borland; David Hammond; Bill King; Christian Boudreau; K. Michael Cummings, *Nicotine & Tobacco Research*, Volume 9, Issue 10 October 2007, pages 1033-1042.

<http://www.informaworld.com/smpp/content-content=a783052257~db=all~order=page>

A 2000 survey of 36,012 young adults entering the U.S. Air Force found that 75% of males and 81% of females incorrectly believed that switching from cigarettes to ST products would not result in any risk reduction, while another 16% of males and 13% of females incorrectly believed that only a small risk reduction would occur. Only 2% of

males and 1% of females correctly thought that a large risk reduction would occur by switching from cigarettes to ST.

Modified Tobacco Use and Lifestyle Change in Risk-Reducing Beliefs About Smoking, Haddock CK, Lando H, Klesges RC, et al, American Journal of Preventive Medicine, 2004 Vol. 27, No. 1, 35-41.

Another survey found that 89% of college freshmen incorrectly believe that ST is just as or more harmful than cigarettes.

Harm perception of nicotine products in college freshmen, Smith SY, Curbow B, Stillman FA, Nicotine Tob Res. 2007 Sep;9(9):977-82.

<http://www.informaworld.com/smpp/content~content=a781712955~db=all~tab=content~order=page>

A survey of more than 2,000 adult U.S. smokers found that only 10.7% correctly agreed that ST products are less hazardous than cigarettes, while 82.9% incorrectly disagreed.

Smoker Awareness of and Beliefs About Supposedly Less-Harmful Tobacco Products, O'Conner RJ, Hyland A, Giovino G, et al, American Journal of Preventive Medicine, 2005, Vol. 29, No. 2, 85-90.

In yet another survey, when asked if they believed that chewing tobacco is just as likely to cause cancer as smoking cigarettes, 82% of U.S. smokers incorrectly agreed.

Informing Consumers about the Relative Health Risks of Different Nicotine Delivery Products, presentation by K. Michael Cummings at the National Conference on Tobacco or Health, New Orleans, LA, November 2001.

The reason for this lack of knowledge is largely due to the 1986 Comprehensive Smokeless Tobacco Education Act, which required three rotating warnings on all smokeless tobacco products (i.e. This product is not a safe alternative to cigarettes. This product may cause mouth cancer. This product may cause gum disease and tooth loss.) The FSPTCA requires even large warnings on smokeless tobacco products and advertisements.

Since there is no evidence that dissolvable tobacco products (or snus) cause mouth cancer, gum disease or tooth loss, those two warnings should NOT be required on dissolvable tobacco products. And since the effect of the “not a safe alternative” warning has only served to mislead smokers to believe that smokeless tobacco products are as hazardous as cigarettes, that warning also should also not be required on any dissolvable smokefree tobacco product.

Authors of a study that evaluated 316 English language websites (none of which were tobacco companies) that contained health risk information about cigarettes and smokeless tobacco use concluded: “The risk from ST is widely conflated with the risk from cigarettes on websites that provide health advice and information. Almost every website had statements that played up the health risks from ST without caveat, making it difficult for consumers to recognize the huge contrast with cigarettes. The quantitative claims of health risks from ST were very often beyond a worst-case-scenario interpretation of the scientific literature. A large portion of websites directly stated or implied that the risks from ST and cigarettes are similar.”

You might as well smoke; the misleading and harmful public message about smokeless tobacco, Carl V Phillips, Constance Wang, Brian Guenzel,

BMC Public Health 2005, 5:31doi:10.1186/1471-2458-5-31

<http://www.biomedcentral.com/1471-2458/5/31>

Smokers Have a Human Right to Truthful Health Risk Information and Access to Less Hazardous Alternatives

Government health agencies (including the FDA) have an ethical duty to truthfully inform smokers that smokefree tobacco products are less hazardous alternatives to cigarettes. Similarly, smokers have a human right to be truthfully informed that smokefree tobacco products are far less hazardous alternatives than cigarettes, and legal and affordable access to these products.

Harm reduction, public health, and human rights: Smokers have a right to be informed of significant harm reduction options, Kozłowski L, *Nicotine & Tobacco Research*, S55-S60, 2002.

http://ash.org.uk/html/regulation/pdfs/hr_kozlowski.pdf

First Tell The Truth, A Dialogue on Human Rights, Deception, and the Use of Smokeless Tobacco as a Substitute for Cigarettes, Kozłowski L, *Tob Control*, 12:34-36, 2003.

http://tc.bmjournals.com/cgi/search?andorexactfulltext=and&resourcetype=1&disp_type=&sortspec=relavance&author1=&fulltext=&volume=12&firstpage=34

No Evidence Smokeless Tobacco Products are Gateway to Cigarette Smoking

Authors of a recently published analysis of NSDUH data concluded that: “Smokeless Tobacco (ST) use has played virtually no role in smoking initiation among White men and boys, the demographic groups among which ST use is most prevalent. There is evidence that, compared with cigarette initiators, ST initiators are significantly less likely to smoke.”

Evidence against a gateway from smokeless tobacco use to smoking, Brad Rodu and Philip Cole, *Nicotine Tob Res* (2010) 12 (5): 530-534. doi: 10.1093/ntr/ntq033

<http://ntr.oxfordjournals.org/content/12/5/530.short>

Using most of the same data, a 2009 SAMHSA report found that, among US residents who had used both cigarettes and smokeless tobacco products in their lifetime, 65.5% used cigarettes prior to smokeless tobacco use, and 31.8% used smokeless tobacco prior to cigarette usage.

Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (February 19, 2009). *The NSDUH Report: Smokeless Tobacco Use, Initiation, and Relationship to Cigarette Smoking: 2002 to 2007*. Rockville, MD.

<http://www.oas.samhsa.gov/2k9/smokelesstobacco/smokelesstobacco.htm>

Smokers Need Additional Smokefree Tobacco Alternatives Since the Vast Majority of NRT Users Switch Back to Smoking Cigarettes

A meta-analysis found that an average of just 7% of those using over-the-counter NRT products remained cigarette free after six months, a 93% relapse rate.

A meta-analysis of the efficacy of over-the-counter nicotine replacement, Hughes JR, Shiffman S, Callas P, Zhang Z, *Tobacco Control*, 2003, Vol. 12, 21-27.

<http://tc.bmjournals.com/cgi/content/full/12/1/21?ijkey=5.ko5/Oz4yutl>

Another recent meta-analysis also found that 7% of NRT remain cigarette free after six months, and that just 2% remain cigarette free after 20 months (a 98% relapse rate).

Effectiveness and safety of nicotine replacement therapy assisted reduction to stop smoking: systematic review and meta-analysis, David Moore, Paul Aveyard, Martin Connock, Dechao Wang, Anne Fry-Smith, Pelham Barton, BMJ 2009;338:b1024

http://www.bmj.com/cgi/content/full/338/apr02_3/b1024

A meta analysis of seven placebo controlled randomised controlled trials involving different NRT products found that just 6.75% of those receiving NRT had quit smoking after six months. While this may have been twice the quit rate compared to placebo, it represents a 93.25% failure rate for smoking cessation, and clearly indicates that smokers need additional and alternative methods of reducing the health risk of cigarette smoking.

Effectiveness and safety of nicotine replacement therapy assisted reduction to stop smoking: systematic review and meta-analysis, David Moore, Paul Aveyard, Martin Connock, Dechao Wang, Ann Fry-Smith, Pelham Burton, BMJ 2009; 338:b1024

<http://www.sciencedirect.com/science/article/pii/S0306460311001572>

While supposedly double-blind clinical trials have found that NRT products double the chances of quitting when compared to using a placebo, skepticism has been raised about the accuracy and reliability of these studies, since it is likely that many participants who were assigned to placebos realized they were not getting nicotine.

The blind spot in the nicotine replacement therapy literature: Assessment of the double-blind in clinical trials, Mooney M, White T, Hatsukami D, Addictive Behaviors, 2004 Vol. 29, 673-684.

http://whyquit.com/studies/NRT_Blinding_Failures.pdf

Precessation treatment with nicotine patch significantly increases abstinence rates relative to conventional treatment, Jed E. Rose, Joseph E. Herskovic, Frederique M. Behm and Eric C. Westman, Nicotine & Tobacco Research 2009 11(9):1067-1075; doi:10.1093/ntr/ntp103.

<http://ntr.oxfordjournals.org/cgi/content/abstract/ntp103>

Skin patches appear to be ineffective smoking cessation aids for those who fail to quit smoking during their first use of NRT, as two published studies on the use of NRT skin patches to quit smoking after an initial failure with NRT found six-month smoking cessation rates of 0% and 1.4%, respectively.

Recycling with nicotine patches in smoking cessation. Tonnesen P, Norregaard J, Sawe U, Simonsen K, Addiction. 1993 Apr;88(4):533-9.

http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=8485431&query hl=2

Double blind trial of repeated treatment with transdermal nicotine for relapsed smokers. Gourlay SG, Forbes Q, Marriner T, et al. British Medical Journal, 1995, Vol. 311, No 7001 363-366.

A survey of 500 U.S. smokers found only 16% agreed that NRT helps people quit smoking.

Attitudes toward nicotine replacement therapy in smokers and ex-smokers in the general public. Etter JF, Perneger TV, Clinical Pharmacol Therapy 2001 Volume 69, 175-83.

An estimated 36.6% of current nicotine gum users have consumed the product for longer than six months, indicating that long-term nicotine maintenance can occur with NRT gum, just as can occur with smokefree tobacco products.

Persistent use of nicotine replacement therapy: analysis of actual purchase patterns in a population based sample, Shiffman S, Hughes JR, Pillitteri JL, Burton SL, Tobacco Control, Vol. 12, 310-316, 2003.

<http://tc.bmjournals.com/cgi/content/full/12/3/310>

Flavored Dissolvable Tobacco Products are Very Similar to Flavored Dissolvable NRT Products

Studies previously cited in these comments found that dissolvable tobacco products have very health/safety risk/benefit profiles as do dissolvable NRT products.

Sugars and other flavorings have been used the manufacture of cigars and smokefree tobacco products for hundreds of years, and there is no credible evidence indicating that youth are more likely to begin using these products compared to other tobacco products.

Dissolvable nicotine lozenges marketed by GlaxoSmithKline as smoking cessation aids (formerly called Commit and now called Nicorette) have been available in different flavorings, including cherry, mint and formerly cappuccino.

<http://www.nicorette.com/quit-smoking-products/nicorette-nicotine-lozenge.aspx?showsplash=true>
<http://www.nicorette.com/quit-smoking-products/nicorette-mini.aspx>

Ironically (or not), critics of flavored tobacco products that receive funding from drug companies have remained silent about strikingly similar flavored NRT products.

Marketing of tobacco to minors violates the 1998 Master Settlement Agreement, laws in all 50 states, and the FSPTCA

Although some anti-tobacco activists continue to publicly accuse tobacco companies of target marketing tobacco products to youth (including dissolvable tobacco products), it is critically important to note that marketing tobacco products to minors violates the 1998 Master Settlement Agreement, statutes in all 50 states, and the FSPTCA.

During the Senate HELP Committee markup of the FSPTCA in 2009, Senators Sherrod Brown and Jeff Merkley (when proposing the amendment to require the FDA to study dissolvable tobacco products) repeatedly accused RJ Reynolds of target marketing the company's new dissolvable tobacco products (i.e. Camel Orbs, Strips and Sticks) to minors. But no evidence was provided indicating that Reynolds (or any other tobacco company) was marketing their tobacco products to minors.

Similar unsubstantiated allegations were made against Star back in 2001/2002 when Citizens Petitions urged the FDA to ban Star's Ariva and Stonewall dissolvable tobacco products. In the past decade, no evidence has been provided indicating that youth use Ariva or Stonewall, or that Star markets its products to minors.

All three of the 2001/2002 Citizen Petitions urging the FDA to ban Star's Ariva and Stonewall also repeatedly referred to the products as "candy like" in an attempt to deceive the agency and the public to believe that Star was marketing to youth. A decade later, and the same false "candy like" references to dissolvable tobacco products has been repeated by those who accuse tobacco companies of marketing the products to minors.

Instead of repeating unsubstantiated accusations to the media, anyone who has any evidence that any tobacco products are being illegally marketed to youth should notify the State AG, State Health Department and/or FDA for enforcement or other remedial action.

Referring to any tobacco product as “candy” or “candy-like” can only encourage youth to use these products, which raises serious concerns about the true motives of those who call tobacco products “candy” or “candy-like”.

Also, since Section 906(d)(3)(A)(ii) of the FDA tobacco laws prohibits the FDA from banning tobacco sales to 18 year olds (the vast majority of whom are 12th grade high school students), it is doubtful that any amount or type of FDA tobacco regulation can substantially reduce tobacco use among 12th graders (or underclass peers/siblings who obtain tobacco from 18 year olds).

Although youth usage of smokeless tobacco products has increased slightly during the past several years, it is likely that many of the new smokeless users are cigarette smokers just as most new adult smokeless tobacco users are cigarette smokers. Dual usage of smokefree tobacco products is a prerequisite for switching to them, which sharply reduces tobacco attributable disease and death risks.

A newly published survey of 14-18 year old adolescents in Finland found that 10% had used NRT products, and that most users were daily smokers. The reasons for NRT use were just try (56%), to quit (33%) and smoking not possible (24%). *Adolescents' self-reported reasons for using nicotine replacement therapy products: A population-based study*, Susanna Raisamo, David Doku, Arja Rimpela, *Addictive Behaviors* Volume 36, Issue 9, September 2011, 945-947. <http://www.sciencedirect.com/science/article/pii/S0306460311001572>

But anti-tobacco activists who demonize dissolvable tobacco products and/or advocate banning them aren't demonizing NRT products or advocating banning NRT products, probably because many of them are receiving drug industry funding to demonize and advocate bans on tobacco very similar tobacco products.

FDA Misrepresents Scientific Evidence about Health Risks/Benefits of Different Tobacco Products

Earlier this year, the FDA grossly misrepresented the scientific evidence about the health risks of different tobacco products at by falsely claiming **"To date, no tobacco products have been scientifically proven to reduce risk of tobacco-related disease, improve safety or cause less harm than other tobacco products"** on its website at <http://www.fda.gov/TobaccoProducts/ResourcesforYou/ucm255658.htm> (Appendix G)

Since the FDA has made false statements about the health risks of different tobacco products, it is critically important that the TPSAC correct that misinformation and truthfully state that dissolvables and other smokefree tobacco products are far less hazardous than cigarettes.

Push Polls aren't Scientific Evidence

During its July 21/22 meeting, TPSAC member Neal Benowitz repeatedly cited findings of a junk science push-poll that deceived youths to believe three new smokefree tobacco products (which most youths hadn't previously seen or heard of) were candy products (by showing them intentionally deceptive look-alike photos), and then asked the youths if they believed the tobacco products looked like candy, and if they might try using them. <http://www.healthyouthva.org/documents/Meltdown.pdf>

The TPSAC should reject this push poll as junk science and anti tobacco propaganda.

FDA Subjectively Instructed the TPSAC to Focus on Insignificant and Hypothetical Health/Safety Risks of Dissolvable Tobacco Products Instead of Conducting an Objective Health/Safety Risk/Benefit Analysis

When instructing its TPSAC on its final report on dissolvable tobacco products and on TPSAC's July 21/22, 2011 meeting, the FDA subjectively instructed its TPSAC to focus its study, report and meeting on potential and hypothetical risks of the products instead of conducting an objective health/safety risk/benefit analysis of the products. The FDA also failed to urge the TPSAC to consider the enormous health benefits smokers could/would obtain if they switched to or substituted dissolvable tobacco products for cigarettes.

Specifically, at <http://www.fda.gov/AdvisoryCommittees/Calendar/ucm257684.htm> the FDA stated: "These discussions will begin the process for the Tobacco Products Scientific Advisory Committee's required report to the Secretary of Health and Human Services regarding the issue of the nature and impact of the use of dissolvable tobacco products on the public health, including such use among children. The final report should take under consideration (1) the risks and benefits to the population as a whole including users and nonusers of tobacco products; (2) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (3) the increased or decreased likelihood that those who do not use tobacco products will start using such products."

In "Questions to TPSAC" for its July 21/22, 2011 meeting, the FDA stated at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM263294.pdf>

1) In response to the information you have been provided for this meeting, discuss the possible public health impact relating to:

- a) marketing of dissolvable tobacco products
- b) perception and use of dissolvable tobacco products by children and adults
- c) abuse liability of dissolvable tobacco products
- d) health risks of dissolvable tobacco products
- e) risk of accidental ingestion of dissolvable tobacco products
- f) features of dissolvable tobacco products that may contribute to tobacco initiation
- g) features of dissolvable tobacco products that may lead tobacco users to singular or dual-use of dissolvable tobacco products instead of quitting"

By encouraging TPSAC to focus on potential and hypothetical health and safety risks posed by dissolvable tobacco products instead of urging TPSACS to conduct an objective health/safety risk/benefit analysis of dissolvable tobacco products, including among individuals who actually consume the products, who can legally purchase/use the products, and who the products are target marketed to (i.e. adult cigarette smokers), the FDA has essentially urged the TPSAC to conduct a deeply biased study and issue a similarly biased report.

If the TPSAC is truly an objective scientific body, it will reject the FDA's instructions to conduct a biased study and issue a biased report on dissolvable tobacco products.

Last year, the FDA similarly urged the TPSAC to conduct a biased study on menthol cigarettes, which the TPSAC obliged by failing to cite any health risks (e.g. loss of funds for the federal State Children's Health Insurance Program, and for state tobacco control and other health programs due to reduced cigarette tax revenue and Master Settlement Agreement payments) or any of the other negative social ramifications that could/would occur if menthol cigarettes were banned (e.g. creation of unregulated, untaxed and potentially violent black markets for menthol cigarettes).

Once again, the TPSAC should reject FDA's instructions to focus on insignificant and hypothetical health/safety risks of dissolvable tobacco products, and instead the TPSAC should conduct an objective health/safety risk/benefit analysis of the products as actually used by consumers.

Disclosure

Since 1990, Smokefree Pennsylvania has advocated policies to reduce tobacco smoke pollution indoors, increase cigarette taxes, reduce tobacco marketing to youth, preserve civil justice remedies for those injured by cigarettes, expand smoking cessation services, and inform smokers that smokefree tobacco/nicotine products are far less hazardous alternatives to cigarettes. Neither William Godshall nor Smokefree Pennsylvania have ever received any funding from a tobacco, drug, e-cigarette or any other company that markets tobacco or nicotine products.

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